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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,700	07/06/2001	Keith D. Allen	R-616	3949

7590 09/04/2002

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EXAMINER
PARAS JR, PETER

ART UNIT	PAPER NUMBER
1632	11

DATE MAILED: 09/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/900,700	Applicant(s) ALLEN, KEITH D.	
	Examiner Peter Paras	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a targeting construct comprising nucleotide sequences homologous to a CRFR2 gene and a method of producing a targeting construct, classified in class 435, subclass 320.1.

II. Claims 5-7 and 9, drawn to cells comprising a disruption in a CRFR2 gene, classified in class 435, subclass 325.

III. Claims 8, 10, and 17-22, drawn to a transgenic non-human animal, particularly a mouse comprising a disruption in a CRFR2 gene, and a method of making the same, classified in classes 800, 800, and 800 subclass 13, 18, and 25.

IV. Claims 11-12, drawn to methods of identifying agents that modulate the expression of a CRFR2 gene or modulate the function of a CRFR2 comprising screening said agents in a transgenic non-human animal, classified in class 800, subclass 3.

V. Claims 13-15, drawn to methods of identifying agents that modulate expression of a CRFR2 gene or function of a CRFR2 in a cell *in vitro*, classified in class 435, subclass 7.2.

VI. Claim 16, drawn to an unknown agent is unclassifiable.

VII. Claim 23, drawn to phenotypic data, in an electronic database, associated with a transgenic mouse, classified in class 702, subclass 19.

The products of Inventions I, II, III, VI, and VII each from the other are distinct each from the other. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function, and different effects. The products of Groups I, II, III, VI, and VII have different chemical structures, are made by different methods, and can be used in different methods which require different technical considerations and materially different reagents. For example, the transgenic animal non-human animal of Group III can be used as a model of disease while the targeting construct of Group I may be used to disrupt a gene in a somatic cell *in vitro*, the cells of Group II may be used to isolate a protein, and the data of Group VII may be used for statistical analysis in a database. Also, the agent of group VI has a different chemical structure from the targeting construct, cells, and transgenic non-human animals of Groups I, II, and III respectively, and may be used in different methods, which require different technical considerations with respect to modulation of a CRFR2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and separate search requirement, restriction for examination purposes as indicated is proper.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between groups IV and V, because their methods appear to constitute patentably distinct inventions, each with a distinct purpose and further comprising distinct methodologies and using different products. For example, the method of Group IV requires the use of a transgenic non-human animal while the method of Group V requires the use of a cell *in vitro*. Because these inventions are distinct for the reasons given above and a separate search is required for each of Groups III and VI, restriction for examination purposes as indicated is proper.

The products of Inventions I, II, III, VI, VII and the methods of Invention IV and V are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function, and different effects each from the other. The products of Groups I, II, III, VI and VII can be used in methods that require different technical considerations and materially different reagents from the methods of Groups IV and V. The method of Group IV can be practiced with products that have different chemical structures than the products of Groups I, II, III, VI, VII. For example, the transgenic animals of Group II may be used to produce antibodies while the method of Group IV may be used to identify agents that modulate the expression of a CRFR2. Further, the method of Group IV may be practiced with agents that have different chemical structures from the agent of Group VI. Because these inventions are

distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and separate search requirement, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Patsy Zimmerman whose telephone number is (703) 308-0009.

Peter Paras, Jr. Pete Paras Jr

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